510(k) Summary

JUL 31 2008

Identification of the submitter:

Submitter:	Andon Health Co., Ltd. No 31, Changjiang Road, Nankai District, Tianjin, P.R. China, 300193
Telephone number:	86-22-6052 6161
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Contact:	Liu Yi
Date of Application:	29/01/08

Identification of the product:

Device proprietary Name:	KD-391 Semi Automatic Electronic Blood Pressure Monitor
Common name:	Noninvasive blood pressure measurement systems
Classification name:	Noninvasive blood pressure measurement system Class II per 21 CFR 870.1130

Marketed Devices to which equivalence is claimed:

Device	manufacture	510(k) number
KD-322	Andon Health Co., Ltd	K052676

Device description:

KD-391 Semi Automatic Electronic Blood Pressure Monitor is Non-invasive blood pressure measurement system for only one person each time. Based on oscillometric and silicon integrate pressure sensor technology, the device is used to monitor systolic, diastolic blood pressure and pulse rate which will be shown on a LCD with an electronic interface module. Buckling a cuff around the left upper arm, the device can analyze the signals promptly and display the results and remember circularly for some sets of data. It can storage and show 60 times measuring result with the day and time. Besides, the devices have the function of blood pressure level classification which is according to WHO standard.

Intended use:

KD-391 Semi Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic

blood pressure and pulse rate on adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual.

Comparison of technological characteristics of new device to predicate devices:

KD-391 Electronic Blood Pressure Monitors has the same principle with predicated device, which utilizes Oscilliometric measurement method to monitor the blood pressure and the result can be shown on the LCD.

Cuff pressure should be displayed on the LCD during inflating process. The user pressurizes the cuff by the inflating bulb manually, which is same with the predicated device.

Comparing with KD-322 Semi Automatic Electronic Automatic Blood Pressure Monitor, KD-391 has some new functions, such as memory 60 times recent test results with time and date, which display on a large LCD, blood pressure level classification according to WHO standard and cuff size range, which from 22cm-48cm.

The accuracy and effectiveness of the extra large cuffs used in KD-391 Blood Pressure Monitor has been validated through the ANSI/AAMI SP-10 standard.

Clinical Tests:

Clinical tests were performed and complied the accuracy requirements of ANSI/AAMISP10-2002. The results meet or exceed the accuracy requirements of ANSI/AAMISP10-2002.

See the submission for more details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Adon Health Co., Ltd
c/o Ms. Mona
7th Floor Hua Qiao Chuang Ye Plaza
No 10, JinPing Road, Ya An Road
Nankai District,
Tianjin, China 300190

JUL 31 2008

Re: K080326
Trade/Device Name: KD-391 Semi Automatic Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 26, 2008
Received: June 30, 2008

Dear Ms. Mona:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K080326

Applicant: Andon Health Co., Ltd

Device name: KD-391 Semi Automatic Electronic Blood Pressure Monitor

Indications for use:

KD-391 Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use _____ AND/OR Over-The-Counter Use YES

Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080326